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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,971	04/13/2000	Sarah Liljegen	19452A-000700US	7002

7590

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,971	LILJEGREN ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7,9-11,13-18,20-28,30,34 and 36-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,7,9-11,13-18,20-28,30,34 and 36-58 is/are allowed.
- 6) ☒ Claim(s) 59-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 10 January 2005 has been entered.
2. The rejection of claims 34, 36-40 and 42-57 under 35 U.S.C. § 112, first paragraph, as comprising new matter is withdrawn in view of Applicant's response filed 10 January 2005, where said response correctly identifies where in the specification said claim are supported (pages 13 and 14 of the Remarks).
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 59-78 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to expression cassettes, methods of using said expression cassettes and plants transformed therewith, wherein said expression

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cassettes comprise a polynucleotide encoding a polypeptide at least 65%-80% identical to SEQ ID NO: 2, or said polynucleotide is at least 65-80% identical to a fragment of SEQ ID NO: 1.

Applicant describes polynucleotides encoding SEQ ID NO: 2 or a fragment thereof that can be used to suppress fruit dehiscence in a transformed plant.

Applicant does not describe polynucleotides encoding a polypeptide 65-80% identical to SEQ ID NO: 2, even such polypeptides comprising a basic helix-loop-helix domain (see claim 64 for example).

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

Applicant acknowledges that this rejection was previously addressed by the Examiner in response to Applicant's arguments in the Office action mailed 18 November 2003 as directed to previously cancelled claims (page 14 of the Remarks).

Applicant argues that the claim language at issue is directed to polynucleotides or polypeptides at least 65% identical to a reference sequence and that this claim language defines a physical and structural property of the invention, as explicitly required by the court in *University of California*. Applicant argues that percent identity to a particular sequence reflects the structure of the nucleic acid, *i.e.* that its primary structure, or nucleotide sequence, is similar to the recited sequence and thus, the description of the claimed invention satisfies the written description requirement as set forth by the court in *University of California* on at least two grounds, *i.e.* structure and physical properties. This argument is not found to be persuasive because the function

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described is not specific, and the structure has not been correlated to a specific function as Applicant implies. The presence of a basic helix-loop-helix domain does not define a polypeptide having IND1 activity, but is present in other transcription factor polypeptides that have very divergent functions from that of IND1. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

5. Claims 59-78 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to expression cassettes, methods of using said expression cassettes and plants transformed therewith, wherein said expression cassettes comprise a polynucleotide encoding a polypeptide at least 65%-80% identical to SEQ ID NO: 2, or said polynucleotide is at least 65-80% identical to a fragment of SEQ ID NO: 1.

Applicant teaches polynucleotides encoding SEQ ID NO: 2 or a fragment thereof that can be used to suppress fruit dehiscence in a transformed plant.

Applicant does not teach polynucleotides encoding a polypeptide 65-80% identical to SEQ ID NO: 2, even such polypeptides comprising a basic helix-loop-helix domain (see claim 64 for example).

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance on how to make and use polynucleotides encoding polypeptide having IND1 activity as stated in previous Office actions. As stated in the Office action mailed 8 May 2002, the art teaches that transforming plants with heterologous genes encoding bHLH transcription factors to produce a desired phenotype, such as the delayed fruit dehiscence of the instant claims, is unpredictable because the heterologous gene product may not regulate all of the required steps needed to produce the desired phenotype (see Quattrocchio *et al* 1998, The Plant Journal 13(4): 475-488, especially the Summary on page 475). The issue of the Yanofsky Declaration filed under 35 USC § 1.132, filed 15 October 2002, has been addressed in the Office action mailed 18 November 2003. The subsequently isolated

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polynucleotides disclosed are not a part of the teachings of the instant specification and do not adequately support the breadth of the instant claims (argument on page 17 of the Remarks). Hence, it remains the Examiner's opinion that it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use the invention as broadly claimed.


Conclusion

6. Claims 5, 7, 9-11, 13-18, 20-28, 30, 34 and 36-58 are allowed.
7. Claims 29-78 are rejected.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
16 March 2005

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.